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APPLICATION NO	FILING DATE	FILING DATE FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.
09/438,185	35 11/11/99	STEPHENS		R	018941-00041
_		HM12/0828 D TOWNSEND AND CREW	٦ [EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

Application No.

Applica (t(s)

Evaminer

Art Unit 1645

Stonhens et al

Office Action Summary

Patricia A. Duffy -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>three</u> MONTH(S) FROM Period for Reply THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will The Considered analys.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) X Responsive to communication(s) filed on Jun 4, 2001 2b) This action is non-final. 2a) This action is FINAL. $31\square$ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 1-10 is/are withdrawn from consideration. 4a) Of the above, claim(s) 1-8 and 10_______ is/are allowed. 5) Claim(s) is/are rejected. 6) X Claim(s) 9 is/are objected to. are subject to restriction and/or election requirement. 7) Claim(s) 8) X Claims 1-10 **Application Papers** 9) $\boxed{\chi}$ The specification is objected to by the Examiner. 10) The drawing(s) filed on ______ is/are objected to by the Examiner. 11)☐ The proposed drawing correction filed on _______ is: a)☐ approved b)☐ disapproved. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) All b) Some* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 18) Interview Summery (PTO-413) Paper No(s). 15) Notice of References Cited (PTO-892) 19) Notice of Informal Patent Application (PTO-152) 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 20) Other: 17) Information Disclosure Statement(s) (PTO-1449) Peper No(s).

Art Unit: 1645

DETAILED ACTION

Sequence Requirements

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures because the specification and claims do not recite the proper sequence identifier in the text of the description after the appropriate amino acid sequence and in the claims according to 37 CFR 1.821(d). Full compliance with the sequence rules is required in response to this office action.

Election/Restriction

2. Applicant's election with traverse of Group II, Claim 9, SEQ ID

NO:1047 (Cpn 1046) in Paper No. 9, mailed June 4, 2001 is acknowledged.

The traversal is on the ground(s) that the examiner must examine independent and distinct inventions and must show that co-examination of all claims would be burdensome. This is not found persuasive because, MPEP

Art Unit: 1645

803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required. The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of Groups I-III are drawn to distinct inventions which are related as separate products capable of separate manufacture, use or sale as described in the previous Office Action. Restrictions between the inventions is deemed to be proper for the reasons previously set forth. As previously set forth, the independent and distinct proteins have no structure in common and encode completely different proteins having completely different physiological activity as such, the search and examination for one, does not encompass the search and examination of any other protein. Applicants statement that it would not be an undue search and examination burden to search and examine 1073 independent and distinct proteins is not persuasive. In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search $\underline{\text{or}}$

Art Unit: 1645

separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-III are classified separately necessitating different searches of issued U.S. Patents. Clearly different searches and issues are involved in the examination of each Group and for the plethora of different open reading frames (SEQ ID Nos:2-1074) in each Group.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-8 and 10 and open reading frames SEQ ID Nos 2-1046 and 1048-1074 of claim 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9, mailed July 4, 2001.

Specification

- 4. The title and abstract of the invention are not descriptive. A new title and abstract are required that is clearly indicative of the invention to which the claims are directed.
- 5. The examiner cannot read an entire portion of the specification because certain portions of the disclosure are illegible. The illegible portion(s) consist of pages 73-122 in their entirety. It is also noted that these pages do not maintain appropriate margins. Applicants are reminded to

Art Unit: 1645

observe appropriate margins such that holes may be punched in the top of these pages in order to affix the pages to the file without the destruction of text.

Applicant is required to submit a substitute specification under 37 CFR 1.125(b). The substitute specification must be accompanied by:
(1) a statement that the substitute specification contains no new matter; and
(2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Applicants should also note the requirements for the sequence identifiers to be associated with the specific corresponding sequences in pages 73-122 as set forth in paragraph 1 *supra*.

Claim Rejections - 35 USC § 112

6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1645

As to claim 9, the claim is confusing because the phrase "the protein" lacks antecedent basis in the claim. The claim is also confusing because it recites non-elected open reading frames SEQ ID NOs:2-1046 and 1048-1074. The claim is also is confusing because it is unclear if the composition is a purified polypeptide that is not further defined in the claim or the protein of the body of the claim. Better language would be --A composition comprising a purified *C. pneumoniae* protein wherein the protein comprises the amino acid sequence set forth in SEQ ID NO:1047 and wherein the protein is present in the composition at concentration of least 50 percent by weight.---.

Allowable Subject Matter

Claim A. An isolated *Chlamydia pneumoniae* protein comprising the amino acid sequence set forth in SEQ ID NO:1047.

Claim B. A composition comprising the isolated protein of claim A and a carrier.

Claim C. The composition of claim B, wherein the isolated protein is present in the composition at about 20-50% by weight.

Art Unit: 1645

Status of Claims

- 7. No claims are allowed.
- 8. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Sunday-Thursday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D. August 24, 2001

> Patricia A. Duffy, Ph.D. Primary Examiner Group 1600